Amgen Inc. v. F. Hoffmann-LaRoche LTD et al

Document 156-4 Filed 11/29/2006

Page 1 of 4

Doc. 156 Att. 3

EXHIBIT 3

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November 14, 2006

VIA E-MAIL & FACSIMILE

Thomas F. Fleming Kaye Scholer LLP 425 Park Avenue New York, NY 10022-3598

Re: Amgen Inc. v. F. Hoffmann LaRoche Ltd., et al. (05-CV-12237 WGY)

Dear Tom:

I write to follow up on our discussion of Friday regarding Roche's draft Protective Order. As we discussed, I have revised your draft Protective Order to address some of Amgen's specific concerns and a redlined copy of that draft is attached hereto. In addition to the particular changes set forth in the draft Protective Order, we disagreed over the import of Judge Young's November 6 Order with respect to a few fundamental issues, as set forth below. You agreed to reconsider your position on those issues and respond to us early this week. I look forward to your comments on the issues outlined below as well as our revisions to the draft Protective Order you have proposed.

First, as I mentioned on the call, the definitions you have proposed for "Confidential Material" and "Highly Confidential Material" are overlapping, highly subjective and virtually indistinguishable. Given the vague and subjective standard you propose to differentiate "Highly Confidential" from "Confidential" information, we are concerned that virtually anything can (and will) be designated as "Highly Confidential," thus precluding the effective involvement and assistance of in-house counsel in the preparation and presentation of this case.

This problem is only compounded by the provisions you propose for challenging over-designation of information as "Confidential" or "Highly Confidential." Under your proposal, a challenge by Amgen to Roche's designation of information as "Highly Confidential" would not result in a redesignation of the information until a "final ruling, including any appeal of such a ruling, interlocutory or otherwise." In other words, even if Judge Young ruled in Amgen's favor, Roche would not be required to re-designate the challenged information until it had exhausted all appeals. We do not believe the Protective Order should grant either party such unilateral power to impede or obstruct the preparation and presentation of this case.

490437_1

DAY CASEBEER
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Thomas F. Fleming November 14, 2006 Page 2

During our call, I sought to elicit your agreement on an objective standard that could be applied to delineate the small amount of information that Roche believes should be treated as "Highly Confidential." You indicated that you were reluctant to state an objective test or set of specific categories to define information that may be designated as "Highly Confidential" before collecting and reviewing your client's information. While I appreciate the challenge in defining categories at the outset of discovery, it is not an insurmountable task and we should be able to fashion an objective standard that can be used to differentiate "Highly Confidential" from "Confidential" information. Moreover, Amgen and Roche clearly need to do so before their internal review and production of responsive information, lest everything by default be designated at the highest level of confidentiality. In short, the failure to set forth an appropriately limited, objective standard now will inevitably lead to a de facto single tier Protective Order whereby the information designated as "Highly Confidential" will entail far more of the information produced than is truly subject to such designation. We do not believe this to be consistent with the letter or the spirit of Judge Young's order. Accordingly, we have revised your proposed form of Protective Order to provide more specific and categorical definitions for "Confidential" and "Highly Confidential" information and believe that such clarity will benefit both parties as well as the Court. We hope you will reconsider your position on this and we look forward to your response.

As you know, Judge Young ruled that the information previously produced in the ITC proceeding shall be treated as "Confidential Material" in this action and he denied Roche's request to redesignate such information. Nonetheless, in the spirit of compromise and in furtherance of a delimited two-tier protective order, we are willing to permit each party to re-designate the information produced in the ITC proceeding in accordance with the "Confidential" and "Highly Confidential" categories proposed in our form of Order.

With respect to Roche's BLA and IND, you voiced the opinion that Judge Young's Order endorsed in full all of the restrictions of the ITC Side Agreement on access and use of Roche's BLA and IND. But Judge Young explicitly endorsed only the terms on pages 6-7 of your motion. We do not understand his order to impose restrictions on outside counsel's access to and use of the BLA or IND beyond those specifically endorsed in his order. Nor has Roche identified any reason to further hinder outside counsel's ability to access, review, or use Roche's BLA and IND beyond the restrictions already imposed by the remainder of the Protective Order. We asked you to reconsider your position on this by early this week.

In addition, we do not believe that Roche has fulfilled its obligation to produce ten electronically searchable electronic copies of its BLA, as required by Judge Young's order. As we discussed, the OCR version of the BLA produced by Roche in the ITC proceeding was not in consecutive page order and included inactive hyper-text links, making it impossible to identify and locate the linked reference documents, analyze the materials, or even confirm that the documents were produced in

490437_1

DAY CASEBEER MADRID & BATCHELDER LLP

Thomas F. Fleming November 14, 2006 Page 3

full. Given these shortcomings, we reiterate our pending request for Roche to produce a complete, electronically searchable and hyper-linked copy of all electronic documents submitted to the FDA (including all documents comprising the BLA) in the electronic form and data format as it was submitted to the FDA. Please see Request for Production Number 37 in Amgen's first set of requests propounded on October 30 for the specific request in this litigation. You agreed to consider our request and provide a response by early this week.

Finally, we believe Judge Young's order subjects all discovery materials to the same procedure for filing with the Court. Your proposed interpretation of Judge Young's order would effectively prevent a party from filing a motion containing the other party's designated information if the Court declined to seal the information. In other words, simply by designating information as "Confidential" or "Highly Confidential," a party can effectively prevent the other party from submitting the designated information to the Court unless the Court first agrees to file the designated information under seal. We do not believe your proposed approach is consistent with Judge Young's Order. Again, we look forward to your prompt consideration and response.

Very truly yours,

DAY CASEBEER

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cc: Peter Fratangelo

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